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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,234	11/13/2003	Lawrence M. Kauvar	388512010410	1178

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/713,234	Applicant(s) KAUVAR, LAWRENCE M.	
	Examiner Nelson Yang	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/20/04</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-16, 17, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. With respect to claim 14, it is unclear what would be considered to be toxic compounds or toxins, since many compounds have the potential to be toxic at sufficient concentrations, and would therefore be considered to be toxins.
4. Claim 14 recites the limitation "the toxin" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to the toxic compound in the first two lines of the claim or something else.
5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps that evaluate the efficacy of a candidate antidote for a toxic compound. While applicant teaches the identification of an antidote to a toxin, applicant does not teach how the efficacy of the antidote would be evaluated.
6. The term "similarity" in claim 17 is a relative term which renders the claim indefinite. The term "similarity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what would constitute sufficient similarity in

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order to identify a compound as a medicament to ameliorate a disease condition. Furthermore, it is unclear what sorts of measurements or means of determination would be used to make this determination.

7. The term "more closely similar" in claim 19 is a relative term which renders the claim indefinite. The term "more closely similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore it is unclear what the profile is being compared with in order to be more closely similar, and what values or ranges would be considered for the profile to be "more closely similar" to that of normal cells.
8. The remaining claims are indefinite due to their dependence on an indefinite claim.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 14-17, 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Ping et al [Ping et al, Isoform-selective activation of protein kinase C by nitric oxide in the heart of conscious rabbits: a signaling mechanism for both nitric oxide-induced and ischemia-induced preconditioning, March 1999, Circ Res, 84, 587-604].
11. With respect to claims 14-17, 19, Ping et al teach a method involving the observation of the isoform-selective translocation of protein kinase C  $\epsilon$  and  $\eta$  and their role in the late phase of

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ischemic preconditioning, as well as the effects of compounds including nitric oxide (NO) donors, such as diethylenetriamine/NO (DETA/NO) (p.590, column 2), NO synthase inhibitors, such as N-nitro-L-arginine (L-NA) (p. 590, columns 1-2), and PKC inhibitors, such as chelerythrine (p. 590, column 2) on protein kinase C isoforms. In particular, the rabbits were divided into different groups, including one that did not receive any treatment, one that received DETA/NO, and one that received (DETA/NO and chelerythrine). Assessment of translocation of PKC isoforms was conducted using standard SDS-PAGE Western immunoblotting techniques with antibodies against PKC isoforms  $\alpha$ ,  $\beta$ ,  $\gamma$ ,  $\epsilon$ ,  $\zeta$ ,  $\theta$ ,  $\iota/\lambda$ , and  $\mu$ ; PKC isoforms  $\beta 1$  and  $\beta 2$ ; and PKC isoforms  $\eta$  and  $\delta$  (p. 591, column 1), with particular focus on the  $\epsilon$  and  $\eta$  isoforms, since DETA/NO induces translocation of those isoforms (p.594, column 2).

12. Claims 14-17, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brick-Ghannam et al [Brick-Ghannam et al, Protein Kinase C (PKC) activation via Human Leucocyte Antigen Class II Molecules, 1991, 266:35, 24169-24175].

13. With respect to claims 14-17, 19, Brick-Ghannam et al teach a method involving the analysis of intracellular localization of protein kinase C (PKC) types  $\alpha$ ,  $\beta$ , and  $\gamma$  in a lymphoblastoid B cell line (abstract, p.24171, column 2). Specifically, Brick-Ghannan et al teach a method that observes that anti-human leucocyte antigen (HLA) class II antibodies cause an increase cytosolic and membrane PKC activity (p. 24169, column 2). Brick-Ghannan et al further teach that transcriptional inhibitors, such as actinomycin D, or translational inhibitors, such as cycloheximide, inhibit the observed increase of PKC activity and quantity (p. 24173, columns 1-2, figs 7A, 7B).

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*Conclusion*

14. No claims are allowed.

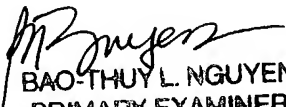
15. The following references are also cited as art of interest: Ping et al [Ping et al, Ischemic preconditioning induces selective translocation of protein kinase C isoforms  $\epsilon$  and  $\eta$  in the heart of conscious rabbits without subcellular redistribution of total protein kinase C activity, 1997, Circ Res, 81, 404-414]

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
4/29/04